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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,018	06/25/2001	Hans O. Ribi	SEGA.004.01US	2628

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EXAMINER	
BENNETT, RACHEL M	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/892,018	RIBI, HANS O.	
	Examiner	Art Unit	
	Rachel M. Bennett	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83 and 85* is/are pending in the application.

4a) Of the above claim(s) *5,26-28,34-37 and 43-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6—25, 29-33, 38-42 , 85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of the amendment filed 10/16/03.

Terminal Disclaimer

1. The terminal disclaimer filed on 10/16/03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 09/602,001 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Specification

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 6-25, 31-33, 38-42, 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribi (US 5685641).

Applicants claim an ingestible comprising a chromic change agent, specifically a mono- or polydiacetylenic compound, other than a liposome that undergoes a color change one or more times in response to at least one physical or chemical triggering mechanism that is other than a binding pair interaction.

Ribi discloses temperature monitoring devices comprising a solvent pervious substrate impregnated with a diacetylene polymer. The device critical temperature is determined by lipid length and structure, the nature of the head group, and the combination of the different chain lengths. The device is prepared by contacting the substrate with a solution of diacetylene

monomer in a solvent which provides impregnation of the substrate with the diacetylene monomer to at least a short distance from the surface. Upon heating above a predetermined temperature, the color of the polymer irreversibly changes so as to be readily distinguishable from the original color. Depending upon the choice of the individual or combination of monomers, the temperature range at which the color change occurs can be anywhere within the range of 25 deg C to 300 deg C. See col. 1, lines 53 – col. 2 line 2. The devices may have specific shapes, in whole or in part, to provide for specific applications. The devices may take the shape of films, tapes, toothpicks etc. See col. 2 lines 25-67. The devices may be used to monitor the temperature of food and hot liquids. For example, the toothpick impregnated with the diacetylene polymer is inserted into the food. See cols. 5-6, examples and claims. Ribi meets the limitation of an ingestible comprising a chromic change agent. Therefore, these claims are anticipated.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ribi (US 5685641) in further view of Food Color Facts (USFDA).

Applicants claim a solid ingestible comprising a diacetylenic compound other than a liposome having a transition temperature in a range of about –10 to 200 deg C and at least one food dye, wherein a combination of said diacetylenic compound and said at least one food dye imparts to said solid ingestible a color of said at least one food dye different from a color of said diacetylenic compound in one of its transitions.

Ribi, as disclosed above, teaches temperature monitoring devices comprising a solvent pervious substrate impregnated with a diacetylene polymer.

The USFDA discloses food color facts. A color additive is any dye, pigment or substance that can impart color when added to applied to food, drug, cosmetic or the human body. Additives are known to be added to sauces, gravies, soft drinks, baked good and other foods. Certifiable color additives are used widely because their coloring ability is more intense than most colors derived from natural products. In addition, certifiable colors are more stable, provide better color uniformity and blend together easily to provide a wide range of hues. Certifiable color additives generally do not impart undesirable flavors to foods. Color additives are known to be added to foods because of color variation throughout the seasons and the effects of food processing and storage often require that manufactures add color to certain foods to meet customer expectations. The primary reasons for adding colors to food include: 1) to offset color loss due to exposure to light, air, extremes in temperature, moisture and storage conditions, 2) to correct natural variation in color, 3) to enhance colors, 4) to provide a colorful identity of foods

that would be otherwise virtually colorless, 5) to provide a colorful appearance to certain "fun foods", 6) to protect flavors and vitamins and 7) to provide an appealing variety of wholesome and nutritious foods that meet customers' demands.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the food taught by Ribi with certifiable dyes disclosed by the USFSA because of the expectation of offsetting color loss due to exposure to light, air, extremes in temperature, moisture and storage conditions, correcting natural variation in color, enhancing colors, providing colorful identity of foods that would be otherwise virtually colorless, providing a colorful appearance to certain "fun foods", protecting flavors and vitamins and providing an appealing variety of wholesome and nutritious foods that meet customers' demands as suggested by the USFDA .

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ribi (US 5685641).

Applicants claim a sugar icing comprising a diacetylenic compound other than a liposome having a transition temperature in a range of about –20 to 350, wherein said diacetylenic compound is triggered by other than a binding pair interaction to change color from a first color to a second color at said transition temperature.

Ribi, as disclosed above, teaches temperature monitoring devices comprising a solvent pervious substrate impregnated with a diacetylene polymer. Ribi does not specifically disclose the food to be sugar icing.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Ribi by adding the temperature monitoring devices

taught by Ribi to sugar icing because of the expectation of achieving or maintaining a certain temperature in order to achieve the desired results as taught by Ribi when using a sugar icing.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Response to Arguments

9. Applicant's arguments with respect to claims 1-4, 6-25, 29-33, 38-42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (571) 272-0589. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

rmb

James M. Spear
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